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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

MARIA DALBOTTEN, Plaintiff, v. C. R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	1:20-cv-00034-SPW **AMENDED COMPLAINT AND JURY DEMAND**

COMES NOW Plaintiff Maria Dalbotten, demanding trial by jury, and for her amended complaint against Defendants, alleges as follows:

PARTIES

1.

Plaintiff Maria Dalbotten is a natural person who is a citizen and resident of the State of Washington.

2.

Defendant C. R. Bard, Inc. (Bard) is a business corporation for profit and a corporate citizen of the State of Delaware with its headquarters in the State of New Jersey.

3.

Defendant Bard Peripheral Vascular, Inc. (BPV) is a business corporation for profit and a corporate citizen of the State of Arizona.

4.

Defendant BPV is a wholly-owned subsidiary of Bard.

JURISDICTION

5.

This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants; Plaintiff and Defendants are citizens of different states; and Plaintiff contends, in good faith, that the amount at issue exceeds seventy-five thousand dollars ($75,000.00) excluding interest and costs.

VENUE

6.

Venue is proper under 28 U.S.C. § 1391(b)(2) because the United States District Court of Montana is the judicial district in which a substantial part of the events giving rise to the claim occurred.

GENERAL ALLEGATIONS

7.

The Defendants are in the business of designing, fabricating, modifying, labeling, distributing, supplying, selling, packaging, marketing and advertising Bard G2 Inferior Vena Cava (IVC) filters, a prescription medical device intended to be implanted into humans.

8.

The IVC is a large vein that returns blood to the heart from the lower body. A Bard G2 IVC filter is a small device implanted in the IVC intended to catch blood clots before they reach the heart and lungs.

9.

Bard G2 IVC filter is an umbrella-shaped device that has multiple limbs fanning out from a cone-shaped head. The limbs of the G2 IVC filter consist of legs with hooks that attach to the IVC wall and curved arms intended to catch or break up blood clots.

10.

On August 23, 2006, John R. Craig, M.D., in Billings, Montana placed a Bard G2 IVC filter in the IVC of Plaintiff Maria Dalbotten incident to treatment for traumatic injuries.

11.

After the implant of the Bard G2 IVC filter and while Plaintiff remained unconscious, medical facility personnel delivered to Plaintiff's mother a pamphlet or brochure published by Defendants and intended for Plaintiff. This document is entitled "G2 Filter System for Permanent Placement." The document included "Patient Questions & Answers."

12.

By this brochure or pamphlet Defendants specifically advised Plaintiff as follows: "The G2 Vena Cava Filter is designed to be a permanent implant and does not need to be removed, repositioned, or replaced." The brochure further advised: "The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter has not be established."

13.

Neither this brochure nor the Defendants by any other means at any time disclosed to or warned Plaintiff that Bard G2 IVC filters would fracture, fragment and migrate to other parts of the body including Plaintiff's heart.

14.

Defendants engaged in fraud, deceit, and concealment in that Defendants knowingly misrepresented the benefits of the G2 Filter and concealed and downplayed its risks so as to maintain sales and stock prices, and to keep consumers and victims like the Plaintiff ignorant of defects in the G2 Filter.

15.

Despite the fact that Defendants knew the G2 IVC Filter was likely to fracture, migrate, tilt, and cause injury or death, Defendants marketed the G2 Filter as being safe and effective.

16.

Defendants provided mandatory scripts to its sales force which required them to falsely tell physicians that the G2 Filter was safe and superior to all other filters.

17.

Defendants' labeling materials downplayed the risks associated with the G2 Filter in that they never reported that the G2 Filter may expose patients to high risks of injury or death.

18.

Defendants never obtained approval from any unrelated entity that the Bard G2 IVC filter was safe and effective for its intended use.

19.

Defendants concealed the fact that according to their own internal safety procedures the G2 filter was deemed not safe for human use.

20.

Defendants knew that the G2 Filter contained characteristics and conditions that resulted in the device not performing as safely as the ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

21.

Defendants marketed the Bard G2 filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." Despite these unsubstantiated claims, Defendants failed to make changes to the G2 filter sufficient to cure the defective and unreasonably dangerous nature of the device.

22.

The Bard G2 filter's design causes it to be of insufficient integrity and strength to withstand normal stresses within the human body so as to resist fracturing, migrating, tilting, caudal migration and/or perforating the IVC.

23.

The Bard G2 Filter suffers from manufacturing defects. The manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The

presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter. The G2 filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. The Bard G2 Filter lacks the strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

24.

By February 2006, six months prior to the implant of the Bard G2 filter into Plaintiff's inferior vena cava, Defendants had determined that the G2 filter was migrating caudally with a "high percentage of caudal migrations accompanied by significant filter tilting and limb displacement." Bard concluded that the severity of these occurrences was "critical."

25.

By March 2, 2006, the Defendants had determined that the Bard G2 IVC filter propensity for caudal migration represented an "unacceptable risk" of serious injury and death. Nonetheless, Defendants took no "preventative action" to warn of the "unacceptable risk."

26.

The Defendants knew migrations, including caudal migrations of Bard G2 IVC filters, caused tilt, perforation, fractures and dangerous migration to other

parts of the body, but failed to take any action to address the severe safety and human health issues created by caudal migrations and resulting tilt, perforation, fractures and migration.

27.

During the summer of 2015, Plaintiff first learned that Bard IVC filters would fracture and migrate to various parts of the body of patients with implanted Bard IVC filters.

28.

In December of 2015, after having experienced chest discomfort Plaintiff contacted Harborview Medical Center in Seattle, Washington and subsequently learned there that her IVC filter had in fact fragmented.

29.

On March 4, 2016, William Kuo, M.D., at Stanford Health Center, in Redwood City, California surgically removed portions of the fragmented G-2 filter from Plaintiff's body. Dr. Kuo was unable to remove a G2 filter fragment that had migrated to and lodged in the right ventricle of Plaintiff's heart.

30.

On May 20, 2016, Nahush Mokadam, M.D., at the University of Washington Medical Center in Seattle, Washington, removed the remaining filter fragment that had migrated to and lodged in the right ventricle of Plaintiff's heart.

31.

The G2 filter implanted in the Plaintiff did not conform to representations contained in its labeling and marketing materials and was unfit for its intended use.

32.

Defendants had actual knowledge of the dangers presented by the G2 filter, yet consciously failed to inform or warn Plaintiff of these dangers.

33.

There is no significant statistical improvement in the outcomes of patients implanted with IVC filters compared with patients treated without IVC filters.

34.

Defendants failed to establish and maintain an adequate quality control and post-market surveillance system to inform Plaintiff and others similarly situated of the dangers of the Bard G2 IVC filter and the necessity of medically monitoring Plaintiff for complications of her G2 IVC filter implantation.

35.

Defendants failed to recall the G2 Filter System from the market.

36.

The Defendants engaged in willful, wanton, gross, outrageous and malicious corporate misconduct in conscious disregard for the safety of Plaintiff and others with Bard G2 IVC filters in place.

37.

As a direct result of the failure, fragmentation and migration of the Bard G2 IVC filter implanted in her IVC, the Plaintiff has incurred over $185,000 in expenses for required medical treatment due to the hazards of the G-2 filter. Plaintiff also suffered mental and physical pain and anxiety.

FIRST CAUSE OF ACTION

(Strict Product Liability Manufacturing Defect)

Plaintiff realleges Paragraphs 1 through 37 of this Complaint and Jury Demand and adopts the same as fully set forth in this First Cause of Action.

38.

At all times relevant to this action the Defendants were engaged in the business of designing, fabricating, manufacturing, modifying, labeling, distributing, supplying, packaging, marketing, advertising and selling Bard G2 IVC filters including the G2 IVC filter implanted in Plaintiff Maria Dalbotten.

39.

Defendants knew and intended that their Bard G2 IVC filter would be used without inspection for defects therein and without knowledge of the hazards involved in such use. The Defendants designed, fabricated, manufactured, packaged, marketed, distributed and sold the G2 IVC filter implanted in Plaintiff's IVC.

40.

This Bard G2 IVC filter, when used for the Defendants' intended purpose, was defective and unreasonably dangerous because the device failed and fractured, causing fragments of the device to migrate to Plaintiff's heart.

41.

The Bard G2 IVC filter implanted in the Plaintiff was defective at the time it left the possession of the Defendants and caused serious injury to the Plaintiff while being used for its intended purpose.

42.

Plaintiff Maria Dalbotten did not know of the substantial danger of usage and implantation of the G2 IVC filter, nor was that danger recognizable to her.

43.

The G2 IVC filter implanted in the Plaintiff was in a defective condition because it was dangerous to an extent beyond that anticipated by Plaintiff and an ordinary user.

44.

At the time the Defendants sold the G2 IVC filter implanted in the Plaintiff's inferior vena cava, the product was in a defective condition because of a manufacturing defect that caused the device to fail and fracture resulting in migration of filter fragments to Plaintiff's heart thereby causing her injury.

45.

As a direct result of the manufacturing defect in the Bard G2 IVC filter and the dangerous condition of this product, Plaintiff incurred damages.

SECOND CAUSE OF ACTION

(Strict Product Liability Design Defect)

Plaintiff realleges Paragraphs 1 through 45 of the First Cause of Action and adopts the same as fully set forth in this Second Cause of Action.

46.

At the time it was sold by the Defendants the G2 IVC filter implanted in the Plaintiff was in a defective condition because it was dangerous to an extent beyond that anticipated by an ordinary user due to its design.

47.

The defective design of the G2 IVC filter caused injury to the Plaintiff.

48.

As a direct result of the design defects in the Bard G2 IVC filter and the dangerous condition of this product, Plaintiff incurred damages.

THIRD CAUSE OF ACTION

(Strict Product Liability Failure to Warn)

Plaintiff realleges Paragraphs 1 through 48 of the Second Cause of Action and adopts the same as fully set forth in this Third Cause of Action.

49.

The Defendants, as sellers of the Bard G2 IVC filter implanted in the Plaintiff, had and continued to have an absolute duty to disclose fully dangers of the product and to warn Plaintiff and those who treated her, on an ongoing basis, concerning the nature, kind and scope of the dangers inherent in use of the Bard G2 IVC filter.

50.

The Defendants sold the Bard G2 IVC filter implanted in the Plaintiff in a defective condition because of failure to warn adequately of those dangers which would not be readily recognized by the ordinary user of the product.

51.

The failure to provide adequate warning of the dangers of the G2 IVC filter implanted in the Plaintiff caused injury to the Plaintiff.

52.

As a direct result of said failure to warn defect in the Bard G2 IVC filter and the dangerous condition of this product, Plaintiff incurred damages.

FOURTH CAUSE OF ACTION

(Express Warranty)

Plaintiff realleges Paragraphs 1 through 52 of the Third Cause of Action and adopts the same as fully set forth in this Fourth Cause of Action.

53.

By both words and deeds, Defendants expressly represented that the Bard the "G2 Vena Cava Filter is designed to be a permanent implant and does not need to be removed, repositioned, or replaced."

54.

Defendants marketed the Bard G2 filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance."

55.

Defendants breached their express warranties because the Bard G2 IVC filter failed to conform to their representations as to the quality of this product, and was not permanent and was not as marketed concerning fracture resistance, centering and migration resistance.

56.

The Bard G2 IVC filter in fact was not permanent and required removal because it fractured and migrated from its original implanted position directly contrary to the Defendants' representations.

57.

As a direct result Defendants' breach of express warranty of their the Bard G2 IVC filter and the dangerous condition of this product, Plaintiff incurred damages.

FIFTH CAUSE OF ACTION

(Implied Warranty of Merchantability)

Plaintiff realleges Paragraphs 1 through 57 of the Fourth Cause of Action and adopts the same as fully set forth in this Fifth Cause of Action.

58.

Defendants are merchants who deal with the promotion and selling of Bard G2 IVC filters and sold the filter implanted in the Plaintiff.

59.

Defendants impliedly warranted that the Bard G2 IVC filter implanted in the Plaintiff's inferior vena cava was at least fit for the ordinary purposes for which such product is used and conform to the promises and affirmations of fact that accompany the product.

60.

The Defendants' breached the implied warranty of merchantability. The Bard G2 IVC implanted in the Plaintiff was not merchantable because it was not fit for the purposes for which the product was used due to the fact that the product fractured and migrated from the implant site to other parts of the Plaintiff's body.

61.

The Defendants' Bard G2 IVC was also not merchantable because it did not conform to the promises and affirmations that accompanied the product.

62.

As a direct result Defendants' breach of the implied warranty of merchantability of their the Bard G2 IVC filter and the dangerous condition of this product, Plaintiff incurred damages.

SIXTH CAUSE OF ACTION

(Implied Warranty of Fitness for a Particular Purpose)

Plaintiff realleges Paragraphs 1 through 62 of the Fifth Cause of Action and adopts the same as fully set forth in this Sixth Cause of Action.

63.

At the time the Defendants sold the Bard G2 IVC filter that was implanted in the Plaintiff, they knew the precise particular purpose for which the Bard G2 IVC filter would be used.

64.

The purchaser and the user of the Bard G2 IVC filter implanted in the Plaintiff relied on the Defendants' skill and judgment to select or furnish a suitable and safe product for use as an IVC filter.

65.

Defendants impliedly warranted that the Bard G2 IVC filter implanted in the Plaintiff's inferior vena cava was at least fit and safe for the particular purpose for which it was used.

66.

Defendants breached the implied warranty of fitness for a particular purpose because the Bard G2 IVC filter could not be safely use for its intended purpose without fracture and part of the filter migrating to Plaintiff's heart.

67.

As a direct result Defendants' breach of the implied warranty that the Bard G2 IVC filter was fit to safely perform the particular purpose for which Defendants intended and the dangerous condition of this product, Plaintiff incurred damages.

SEVENTH CAUSE OF ACTION

(Fraudulent Concealment)

Plaintiff realleges Paragraphs 1 through 67 of the Sixth Cause of Action and adopts the same as fully set forth in this Seventh Cause of Action.

68.

In marketing, distributing and selling their Bard G2 IVC filter, the Defendants concealed material facts from Plaintiff and her healthcare providers related to the G2 filter.

69.

The Defendants concealed from Plaintiff and her healthcare providers the material fact the Bard G2 IVC filter was unsafe and not fit for its intended purpose and reasonably foreseeable use.

70.

The Defendants concealed from the Plaintiff and her healthcare providers the material fact the Bard G2 IVC filter posed significant and dangerous health risks to Plaintiff.

71.

The Defendants concealed from the Plaintiff and her healthcare providers the material fact there were additional side effects related to implantation and use of the Bard G2 IVC filter that were not accurately and completely reflected in Defendants' communications concerning the device.

72.

The Defendants concealed from the Plaintiff and her healthcare providers the material fact that the Bard G2 IVC was not adequately tested to withstand normal placement within the human body.

73.

The Defendants concealed from the Plaintiff and her healthcare providers the material fact that Defendants knew that the G2 IVC presented a substantial risk of fracture and migration from the implant site to other parts of the human body.

74.

As a direct result of Defendants' fraudulent concealment of dangers of the Bard G2 IVC filter, Plaintiff incurred substantial damages.

EIGHTH CAUSE OF ACTION

(Constructive Fraud)

Plaintiff realleges Paragraphs 1 through 74 of the Seventh Cause of Action and adopts the same as fully set forth in this Eighth Cause of Action.

75.

Defendants have for many years known of the dangers of the Bard G2 IVC filter and that persons implanted with the G2 filter were in fact being harmed.

76.

Defendants had and continued to have an absolute duty to disclose fully and to warn Plaintiff and others similarly situated, on an ongoing basis, of the nature, kind and scope of the dangers inherent in use of the Bard G2 IVC filter, the potential hazards of permanent placement of the filter and the need to remove the filter when no longer medically indicated in order to avoid serious health risk and injury to the Plaintiff.

77.

Defendants breached their duties of full disclosure and warning, as set forth in the preceding paragraph. Defendants have misrepresented and continue to misrepresent, downplay, and conceal material facts, thereby gaining an unfair advantage, by deception, over Plaintiff to her prejudice, all in violation of § 28-2-406, Montana Code Annotated, and the common law of Montana.

78.

As a result of Defendants' constructively fraudulent and deceitful acts, Plaintiff's interests in health and safety were compromised because she relied upon the Defendants' misinformation to her detriment and incurred substantial damages.

NINTH CAUSE OF ACTION

(Intentional and Malicious Acts and Omissions)

Plaintiff realleges paragraphs 1 through 78 of the Eighth Cause of Action and adopts the same as if fully set forth in this Ninth Cause of Action.

79.

Plaintiff's injuries from failure of the Bard G2 IVC filter implanted in her IVC were caused by the Defendants' intentional and malicious acts and omissions.

80.

The Defendants both knew of facts and intentionally disregarded facts that created the high probability of injury to the Plaintiff; deliberately proceeded to act in conscious and intentional disregard of that high probability of injury to the Plaintiff; and deliberately proceeded to act with indifference to the high probability of injury to her.

81.

As a direct result of the Defendants' intentional and malicious acts and omissions, Plaintiff Maria Dalbotten suffered substantial damages.

DAMAGES

82.

As a direct and legally sufficient result of the unlawful conduct of the Defendants, Plaintiff incurred significant medical expenses.

83.

As a direct and legally sufficient result of the unlawful conduct of the Defendants, Plaintiff experienced great physical pain and suffering and mental distress.

84.

As a direct and legally sufficient result of the unlawful conduct of the Defendants, Plaintiff suffered loss of and damage to her established course and way of life.

PUNITIVE AND EXEMPLARY DAMAGES

85.

The Defendants acted with utter and complete disregard for the rights and interests of Maria Dalbotten. The conduct of the defendants was so malicious, wanton, willful, and egregious as to justify an award of punitive or exemplary damages to punish the Defendants and to serve as an example to such Defendants and other similarly situated entities that conduct of the kind engaged in by the Defendants is unacceptable in our society and will not be tolerated.

JURY DEMAND

Plaintiff demands trial by jury.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment against defendants as follows:

1. For a full measure of reasonable compensation for Plaintiff's medical and related expenses caused by the Defendants' unlawful conduct.

2. For a full measure of reasonable compensation for Plaintiff's physical pain and suffering and mental distress caused by the Defendants' unlawful conduct.

3. For a full measure of reasonable compensation for Plaintiff's loss of enjoyment of life caused by the Defendants' unlawful conduct.

4. For punitive and exemplary damages against Defendants in amount sufficient to discourage and to prevent recurrence of the kind of egregious misconduct engaged in by the Defendants.

5. For costs and disbursements incurred herein.

6. For such other and further relief as to the Court may seem just.

DATED this 26th day of June, 2020.

NICHOLAS P. SCARPELLI, JR.

TOM L. LEWIS, P.C.

By /s/ Tom L. Lewis
Tom L. Lewis
Attorneys for Maria Dalbotten

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Amended Complaint and Jury Demand was served upon the following counsel of record by the means designated below this 26th day of June, 2020.

[ ] U.S. Mail [ ] FedEx [ ] Hand-Delivery [ ] Facsimile [x] ECF [x] Email Transmission`	Mr. Ian McIntosh Crowley Fleck, PLLP 1915 South 19th Avenue P. O. Box 10906 Bozeman, MT 59719 *Attorneys for Defendants*
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